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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FRIEND, TOMAS H F

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 06/17/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary*file copy*

Applicati n N .

09/582,971

Applicant(s)

PENNINGTON, STEPHEN ROY

Examiner

Tomas Friend

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 6, 14 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-13, 15-29 and 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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Detailed Action

Change of Examiner's Name

The name of the examiner of this application has changed from Thomas Prasthofer to Tomas Friend.

Status of the Application

Receipt is acknowledged of a response to a restriction requirement with amendment on 25 March 2002 (Paper No. 10).

Status of the Claims

Claims 1-36 are pending in the present application. Claims 6, 14, and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10. Claims 1-5, 7-13, 15-29, and 31-36 are pending and examined on their merits.

Response to Restriction and Election of Species with Traverse

Applicant's election without traverse of Group I, claims 1-5, 7-13, 15-29, and 31-36 in Paper No. 10 is acknowledged.

Objections to the Specification

1. The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claims Rejections - 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (new matter). New claim 34 recites “*a pre-selected mass spectrometry-based characterization of a target protein to serve as a reference standard.*” The specification does not appear to support the recitations of “*pre-selected mass spectrometry-based characterization*” or using such to serve as a “*reference standard.*” Applicant has not indicated where support for the newly added claim can be found in the specification. In accordance with MPEP 714.02 applicant can overcome this rejection by specifically pointing out support for this amendment made to the disclosure.

Claims Rejections – 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-5, 7-13, 15-29, and 31-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, method step (B) ii., it appears that the selection of an antibody that binds to a protein of interest is achieved without requiring the subsequent method steps (C)-(E).

Consequently, the metes and bounds of the method step are unclear because it would not make sense to one of ordinary skill to “*select*” or identify an antibody in method step (e) that has already been “*selected*” in method step (B). Clarification is requested.

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B. In claim 1, it is not clear how method steps C(i) and/or C(ii) differ from method step B(ii). Or if these steps can be accomplished simultaneously. The frequent usage of “*and/or*” makes the interpretation of the claim difficult, particularly when used in several consecutive steps. Clarification is requested.

C. Claim 1, method step C(ii), appears to require that a mixture of proteins be used in method step C(i) by reciting “*after removing any proteins which have not bound, eluting the at least one protein that has bound.*” Method step C(i), however, allows the use of only one protein and only one antibody. Clarification is requested.

D. Claim 1, read in its simplest form, reads on a method of identifying an antibody that binds to a protein by:

- A) obtaining a mass spectrometry based characterization of the protein,
- B) using the protein to select an antibody that binds to the (single) protein,
- C) screening the (single) antibody by adding it to the single protein that was used to select the antibody then removing any unbound protein and eluting the bound protein,
- D) subjecting the single eluted protein to a mass spectrometry based characterization, and
- E) by comparing the mass spectrometry based characterization obtained in steps (A) and (D), identifying the single antibody that bound to the single protein.

The sequence of steps does not appear to be productive. One of ordinary skill in the art would not know how to interpret the metes and bounds of the claim because the simplest reading of the claimed invention does not appear to make sense. Clarification is requested.

E. In claims 1, 15, 16, 34, and 36 the metes and bounds of “*mass spectrometry based characterization*” are not clear. One of ordinary skill in the art would not know if a characterization “*based*” upon mass spectrometry is to be interpreted the same as a characterization that is directly generated by a measurement made using a mass spectrometer. Clarification is requested.

F. In claim 1, method step (C) ii., it is not clear what the protein(s) is (are) eluted from. It is not clear, for example, if the proteins are eluted from soluble antibody(ies), immobilized antibody(ies), or each other. Clarification is requested.

G. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

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§ 2172.01. The omitted steps are: method steps that would allow one to obtain a theoretical mass spectrometry based characterization. One cannot, for example, obtain such a characterization of a protein of interest without knowing the sequence of the protein of interest.

H. In claim 2, it is not clear at what point in the method of claim 1, the “*one or more proteins*” are to be separated by 2D electrophoresis. The metes and bounds of the term “*separated*” cannot be interpreted for “*one protein*” so the claim is also unclear with respect to the term “*separated*.”

I. In claim 4, the metes and bounds of the term “*one of more proteins*” are not clear. The term also lacks antecedent basis in claim 1.

J. In claims 5 and 29, the metes and bounds of the term “*shotgun method*” are not clear. One of ordinary skill in the art would not be able to determine what methods are intended by applicant to be included with or excluded from the scope of the claim.

K. Claim 7 recites “*wherein the antibodies generated in step (B)(i.) are immobilized,*” but generating antibodies is an optional step. It is not clear how this claim further limits claim 1 when antibodies are not generated.

L. In claims 8 and 20, it is not clear what “*remaining binding sites*” are to be blocked.

M. Claims 10 and 22-27 recite the limitation “*the eluting agent.*” There is insufficient antecedent basis for this limitation in the claim.

N. The metes and bounds of the term “*volatile reagent*” in claims 10 and 22-27 are not clear. One of ordinary skill in the art would not know what degree of volatility a reagent would have to be interpreted by applicants to be volatile, nor would one of ordinary skill know how volatility is to be measured to satisfy the limitations of the claims.

O. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP

§ 2172.01. The omitted steps are: method steps that would allow one to obtain a theoretical peptide mass profile. One cannot, for example, obtain such a profile for an unknown protein.

P. In claim 12, method steps (d)-(f), it appears that the monoclonal antibody(ies) raised may never be contacted with the protein used to generate it (them). One of ordinary skill in the art would not be able to interpret the claim because there is no limitation requiring the mass profiles obtained in steps (d) and (b) to include profiles from the same protein or complex mixture of

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proteins (method step (d) recites “*adding the or another complex protein mixture to the one or more monoclonal antibodies*”).

Q. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: method steps that would allow one to obtain a theoretical peptide mass profile. One cannot, for example, obtain such a profile for an unknown protein (method step b).

R. In claim 13, method step (c), it appears that a complex protein mixture can be used to generate antibodies against a protein that is present in a different complex protein mixture. Clarification is requested.

S. In claim 13, method step (f), the metes and bounds of the phrase “*monoclonal antibodies of potential interest for a monoclonal antibody library*” are not clear. One of ordinary skill in the art would not know what applicant considers to be “*of potential interest*.” If, for example, the ability to bind a particular protein or set of proteins is the requirement for monoclonal antibodies to be “*of potential interest*,” this should be recited in the claim.

T. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: specific, identifiable method steps for performing the claimed method including method steps that would allow one to obtain a theoretical mass spectrometry based characterization. One cannot, for example, obtain such a characterization for an unknown protein.

U. In claim 15, the metes and bounds of “other protein characterization” are not clear. One of ordinary skill in the art would not be able to determine what characterizations are included within or excluded from the scope of the claims.

V. Claim 16 is not clear because it appears to contain a typographical error in line 1.

W. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: specific, identifiable method steps for performing the claimed method including method steps that would allow one to obtain a theoretical mass spectrometry

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based characterization. One cannot, for example, obtain such a characterization for an unknown protein.

X. Claim 17 recites the limitation “*the peptide mass fingerprint.*” There is insufficient antecedent basis for this limitation in the claim.

Y. Claim 19 recites a limitation to the antibodies generated in claim 1, method step (B) i., which is an optional step. It is not clear how claim 19 further limits claim 2 (which depends on claim 1) since the limitation does not necessarily apply.

Z. In claims 31-33 and 35, it is not clear if the limitation to the mass spectrometry based characterization applies to both recitations of mass spectrometry based characterization in the independent claims or to only the first or only the second recitations. Clarification is requested.

AA. In claim 34, the metes and bounds of “*a pre-selected mass spectrometry-based characterization of a target protein*” are not clear. Clarification is requested.

BB. Claim 12 recites the limitation “*selecting one or more hybridomas clones of interest.*” There is insufficient antecedent basis for this limitation in the claim.

Claims Rejections – 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1, 4, 13, 16, 17, 31, and 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Yates, III et. al. U.S. Patent No. 6,017,693 (January 2000).

The Yates, III et. al. reference discloses mass spectrometry-based methods for identifying proteins and application of the methods (abstract). A protein sequence database is used to predict fragment spectra comparison with an experimentally derived fragment spectrum (abstract). Column 20, lines 16-38, discloses the use of the cited method to detect virally infected cells. An antibody is produced that recognizes a specific epitope of a protein (i.e. a

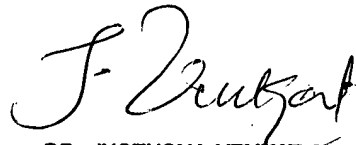
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monoclonal antibody) common to viral pathogens. The antibody is used to isolate the viral protein (protein of interest) from other proteins (of a complex mixture). The protein bound by the antibody and eluted from the antibody is analyzed by mass spectrometry and the experimental data is used to search a database of predicted mass spectrometry data. The making of a monoclonal antibody against a specific epitope of a protein inherently involves utilizing a purified (resolved) protein to generate the antibody and inherently results in the generation of more than one antibody. One of ordinary skill in the art would immediately envisage using a purified viral protein to generate monoclonal antibodies and screening those antibodies to select those that bind the desired epitope. Accordingly, the Yates, III et. al. reference anticipates present claims 1, 4, 13, 16, 17, 31, and 33-35.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday, Tuesday, Friday, and Saturday 8:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.


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SUPERVISORY PATENT EXAMINER
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Tomas Friend, Ph.D.
09 June 2002